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REVIEW

Research in general dental practice*

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Abstract
Spurred by an initiative by the National Institute of Dental and Craniofacial Research in the USA, this article presents the need for a change in clinical dental research towards practice-based research. It outlines the shortcomings of past and present-day research in dentistry, with emphasis on the lack of clinical relevance of much of the research performed. The slow transfer of sound research findings to clinical practice is also a major problem. The article reviews some problems related to restorative dentistry and how they have adversely affected general dental practice. Practice-based research places emphasis on the problems experienced by clinicians in the routine care of patients. Clinicians should be linked together in research networks. The problems they face in dental practice and the clinical experience they have will form the basis for studies by the network. Experienced clinical researchers will provide guidance and statistical support for the studies initiated by the clinicians.

Key Words: *Clinical experience, clinical networks, clinical research*

Introduction

Major research achievements have been made related to dental caries and periodontal disease. A wealth of data has accumulated over recent decades from research mainly sponsored by federal agencies such as the National Institute of Dental and Craniofacial Research (NIDCR) at the National Institutes of Health (NIH) in the US, Medical Research Councils, and academic institutions in many countries, the dental industry, and from miscellaneous sources. Nonetheless, relative to the billions of dollars spent on dental research during the past 50 years, the impact on general dental practice has been only moderate. It is important in this context to analyze why the outcome has not been more substantial.

In looking at the research programs supported by the major funding agencies, most programs have distanced themselves from clinical practice. Laboratory studies have become a major part of the agenda because they can be designed to allow hypotheses to be tested. Whenever clinical studies have been supported, the focus usually has been on randomized, controlled clinical trials. The clinical relevance of these laboratory studies and clinical trials must be challenged because their designs and applicability are remote from everyday, real-life clinical dentistry [1,2].

General dental practice

It must be recognized that clinical practice is not always scientific in the true sense of the term. In fact, the effectiveness of most clinical procedures is not scientifically documented. This situation is not unique to dentistry; the same problems are found in medical practice. Only about 15% of medical interventions are supported by scientific evidence [3].

Nonetheless, the dental profession and the public have come to view dental practice as largely successful. This positive perspective is to a large extent rooted in clinical experience rather than scientific investigations. Thus, the potential for future improvements in clinical practice might best begin by relying on experience from clinicians who are engaged in daily practice. This clinical experience is an untapped resource that might more expeditiously lead the way to improved clinical practice than rigorously controlled studies.

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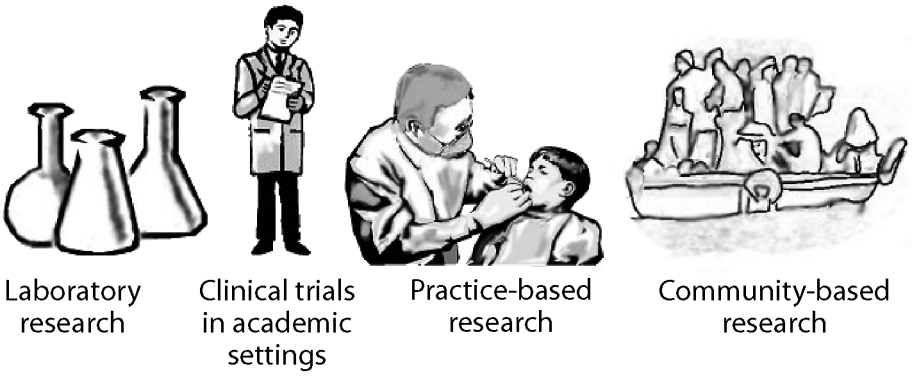

Figure 1. Clip art illustration of different types of research.

By combining clinical expertise and scientific research, the potentials for establishing an evidence base is likely to increase. Thus, experienced practitioners linked to clinical investigators can open up possibilities to improve the effectiveness of dental care provided in daily clinical practice. Problems defined and outlined in clinical settings may then be presented to basic scientists for detailed investigations, closing the feedback loop for further studies to advance research that will ultimately impact daily practice.

Different types of research exist (Figure 1). Because of its capacity for using highly controlled study designs, laboratory research will typically produce the most scientifically rigorous documentation, but not necessarily the data that may be clinically the most useful. Moving from left to right on Figure 1, the scientific strength decreases and the clinical applicability increases. Well-done randomized clinical trials offer the scientific rigor of a true experiment, but trials are often done on highly selected patient groups, by specially trained clinicians for whom there are no time constraints, and with a level of control that cannot or would not be practical in daily clinical practice. Practice-based studies offer the advantages of being conducted by "real-world" clinicians in a clinical setting where the population receives its dental care in contrast to the types of patients who are recruited to academic or highly specialized facilities. However, these investigations do not have the same scientific strength as controlled studies. Finally, the research setting at the right of Figure 1, comprising community-based studies, offers the important advantage of including individuals who do not enter the dental care system, thereby allowing investigation of disease that is not altered by clinical treatment. Fluoride research and the application of fluoride in practice are examples of approaches that are well documented both scientifically and clinically.

Surveys characterizing the features of general dental practice in the US show that restorative dentistry and caries diagnosis and prevention comprise the bulk of dentists' time [4,5], although the time spent on these procedures is declining. Other treatments, including extractions/oral surgery, periodontal, endodontic, and prosthodontics therapies, together comprise less than a third of the treatment time. Therefore, changes in restorative dentistry will have a marked impact on general dental practice.

Cariology and preventive dentistry are the fundamental bases for restorative dentistry. Therefore the extent, depth, and quality of teaching and practice in these areas will have a marked effect on restorative dentistry. Surveys of the teaching of cariology in North America have shown that many dental schools lack detail and depth in this important area of restorative dentistry [6,7]. Without a close association between cariology, the field of restorative dentistry tends to become technique oriented, i.e. "drill and fill" oriented. Much can be gained merely by applying the research results already available.

The research foundation in cariology and preventive dentistry has long been in place. It has been implemented to a large extent for the main part of the population in some countries, including the Scandinavian countries, but its full implementation in general dental practice is long overdue in many countries, including North America [4]. The changes in the practice of restorative dentistry with emphasis on preventive dentistry, arresting initial caries lesions, and minimally invasive preparations [8] are of paramount importance for the dental profession and the public at large.

Research achievements in restorative dentistry

The changes in the practice of restorative dentistry that have occurred during the past 50 years have focused mainly on the development of new restorative materials and clinical techniques. However, clinical research has not been at the forefront of the developments and "trial and error" has been the most common approach, usually without any documentation of the results. The changes in the practice of restorative dentistry have therefore been slow and the research foundation for improvements has often been laid only after the changes have been introduced in general dental practice.

When exploring the literature for major research breakthroughs in restorative and preventive dentistry, the "fluoride story" still surfaces as *the* major accomplishment. It was indeed a major achievement with respect to the prevention of dental caries. However, the groundwork for this major research achievement was completed 70 years ago, and it took almost 40 years from the time the basic research was initiated until it had an effect on caries prevention for the public at large [9]. The implication of the positive effect of fluoride in caries prevention still has not been made available to large parts of the world population, partly because of priority on other public health measures, and also because an active initiative is required to inform the profession and the public on how to implement the documented advantage of this simple, safe, and cost-effective disease-preventive measure.

When the overwhelming evidence presented on caries preventive measures was put into practical use in some European countries, it resulted in a reduction in the number of applicants to dental schools, the closure of dental schools, and an increased number of underemployed and unemployed dentists [10]. It was also recognized that the caries process could be arrested and that surgical intervention should be postponed until prevention was no longer feasible, which enhanced the opportunities for a preventive approach to restorative dentistry.

Surveys of teaching programs in North American dental schools [6,7] have indicated that the threshold for surgical intervention was in enamel in more than a third of the dental schools, despite the fact that enamel lesions can be arrested and/or remineralized, i.e. the lesions do not require operative intervention. An unpublished follow-up study among almost 300 clinicians in general practice in Florida indicated that 60% of practitioners still surgically treated caries detected in enamel only [11]. A survey of state and regional dental board examination requirements revealed that caries lesions in enamel that may have been arrested and healed were used in 72% of the states [12]. Thus, the teaching of cariology in North America is not in conformity with the research data available, nor with the recommendations from the national dental association [8].

A major development in restorative dentistry, largely sponsored by the dental industry, was the introduction of the high-speed dental hand piece. Its use has simplified the preparation of teeth, possibly too much so, because little attention has been paid to the loss of tooth tissues and the more complex scenarios that follow when repairs and replacements become necessary. Biological investigations using this new equipment showed that iatrogenic effects can adversely affect the dental pulp in newly erupted teeth, especially if cooling of the rapidly rotating bur is inadequate [13–16].

An evaluation of the biological effects of restorative dentistry and of caries progression requires clinical research in general practice because conclusions may be heavily dependent on how the research design is implemented. Such investigations will harvest the results of documented data. A combination of technology transfer and implementation of established research data collected by clinicians would have the potential for major changes in the practice of restorative dentistry.

Effect of lack of research

The initial example provided about the positive effect of fluoride research highlights how slow implementation of a significant research finding delays the oral health benefit to the public. Examples that follow illustrate scenarios of changes initiated prior to the establishment of a sound research foundation for treatment.

A sense of urgency to replace the poorly functioning silicate cement as a tooth-colored restorative material seemed to have overshadowed the need for a sound research foundation prior to using new tooth-colored restorative materials in general dental practice. The use of cold-curing acrylics as restorative materials in the late 1940s/early 1950s ended up as a failure due to the lack of appropriate premarketing biological and clinical evaluation of the materials. The treatment often resulted in pulp necrosis, the need for endodontic treatment, and/or extraction of teeth. This negative outcome was soon clinically apparent and subsequent research substantiated the clinical observations. An effective clinical reporting system alone could have minimized this disaster that primarily affected anterior teeth.

The introduction of new generations of tooth-colored restorative materials in dental practice, the resin-based composites, represented another clinical challenge where the lack of documented efficacy prior to their use in practice resulted in early failures, especially when these materials were placed in stress-bearing areas of the dentition. The initial short longevity of these restorations resulted from failures caused by a variety of factors, including the inferior quality of the materials, the unexpected technique sensitivity associated with their placement, and the lack of education and training in the use of these materials in dental schools [17,18]. Apart from the expenses associated with the replacement of these restorations, the loss of tooth tissue as a result of frequent replacements caused additional problems by necessitating more comprehensive treatment than would otherwise have been required.

The initial negative clinical experience with the use of these restorative materials should have signaled an urgent need for caution against their further use, but in the name of esthetics the continued use of these materials resulted in industrial development of new and improved resin-based materials. This development took time, and the cost to patients because of the

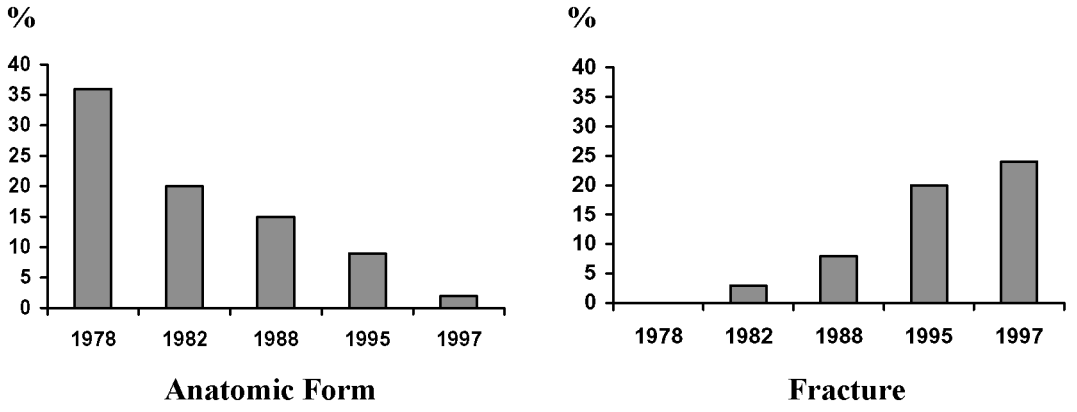

Figure 2. Bar graphs showing loss of "anatomic form", indicating material degradation/wear, and "fracture" as reasons for replacement of composite restorations expressed as percentages of all replacements at various time intervals compiled from different Scandinavian cross-sectional practice-based studies using basically the same methodology [38].

slow progress was enormous, not only financially, but also as a result of the loss of tooth tissues caused by frequent replacements of failed restorations [19–23]. Improvements of the materials also resulted in changes in the reasons for replacement of composite restorations (Figure 2).

The composite materials of the 1990s and the attention to didactic and clinical teaching of resin-based composite materials have resulted in esthetic restorations that have an improved longevity compared with those described in earlier studies [24]. However, it took almost 30 years to reach this stage. It is not known how much of the increased longevity is due to improved material quality and how much to improved clinical techniques. Research in general dental practice might have provided the information necessary to prevent the extensive use of this restorative technique until it was satisfactorily developed.

Long-term practice-based studies of restorations in primary teeth have provided data related to the selection of materials as alternatives to amalgam [25–28]. Fracture of restorations was the main reason for failure of restorations in primary teeth and resin-modified glass ionomer restorative and compomer materials were considered appropriate restorative materials for primary teeth. Large, practice-based studies have recently been initiated to establish the quality of resin-based Class II restorations in permanent teeth of adolescents [29]. Such studies are long overdue.

The rate of progression of some restoration defects is frequently unknown, which tends to lead to "preventive replacement" of restorations [30] with minor defects that may never progress to a stage where they cause damage to the involved tooth or compromise the esthetics to an extent that may be of concern to the patient. Other defects, e.g. bulk fracture of a restoration or fracture of a large part of a tooth, may call for immediate replacement. Marginal degradation, on the other hand, may take years to develop to a stage that requires replacement of the restorations. The clinical diagnosis of secondary (recurrent) caries also invariably leads to replacement, although it is commonly accepted that lesions may vary in size and the rate of progression has never been studied. A differentiation of active and arrested secondary caries lesions is rarely done. These defects are also difficult to differentiate from stained margins on tooth-colored restorations [31]. Furthermore, since no definition exists regarding the degree of failure that results in permanent damage to a tooth, it is inherent that variations in clinical judgment will prevail. Moreover, calibration in clinical judgment of restorations is seldom included in the dental curriculum. In addition, clinicians usually assess their own work by monitoring patients in their own practices during regular recall visits, and the outcome of such evaluations may differ from that obtained when examining restorations placed by others.

The above examples underline the need for a change in the direction of research in restorative dentistry—an area that is at the core of general dental practice and that affects virtually the entire population in industrialized countries. A multifaceted approach to restorative dentistry is needed; an approach that involves the research community, clinicians in practice, and dental education in its widest sense, including continuing dental education, as well as patient education.

Restorative dentistry

Two crucial events impact on the long-term outcome of restorative treatment: (1) Deciding when to place the first restoration in any tooth and (2) the need for replacement of restorations.

Caries preventive measures have been shown to be effective, and numerous studies have attributed the decline in caries primarily to various forms of fluoride treatment [32–35]. More than 90% of all first restorations are done in the treatment of primary caries [36,37]. Some months or years after restorations have been placed the need will arise for replacement of

restorations associated with clinically diagnosed failures. In fact, about 70–80% of all restorations placed in general dental practice used to be replacements [38]. More recent studies indicate that about 50% of all restorations placed were replacements of failed restorations [39–42]. Despite the fact that well-established and documented caries-preventive measures have long been in place, the surgical treatment of caries still represents a major workload in general dental practice.

After the first restoration is placed, the life span of the restoration becomes a good measure of the effectiveness of the treatment. Longevity of restorations and the cost of placing and replacing restorations provide an estimate of the life-long cost of restorative treatment. With the life expectancy of patients at least 75 years, restorations placed at the age of 15 require a 60-year perspective to estimate the life-long cost of restorative dentistry [43].

It is well known to patients and clinicians alike that "permanent" restorations have a limited life span. Many factors affect the longevity of dental restorations, and they may be subdivided into three categories: the clinician, the restorative material, and the patient [2,44]. For indirectly prepared restorations, the quality of the laboratory work also plays a role. Clinicians are the most important factor in this context, not just because they make the diagnosis, but also because they have a strong impact on the selection of the restorative materials to be employed. Furthermore, the diagnosis of failed restorations remains with the clinician. In addition, the responsibility for instructions provided to patients on oral hygiene, information on other caries preventive measures, and monitoring of compliance rest with the clinician. Thus, the skills of the clinicians, their knowledge base, and their acceptance of scientific data are the most important components in this context.

The reasons for replacement of amalgam restorations in general practice have been established in numerous cross-sectional studies in general practice over the past 60 years and for tooth-colored restorations over the past 25 years. Viewed over time, the reasons for failure of amalgam restorations have remained similar, while the reasons for replacement of composite restorations have changed markedly. The clinical diagnosis of secondary (recurrent) caries has prevailed; not only for all types of directly placed restorations, but also for indirect restorations [2,38,45–49].

Secondary caries is an ill-defined clinical diagnostic parameter [50] and it is difficult to differentiate from stained cavosurface margins [31]. The scanty research that has been published related to secondary caries indicates that its microbiology is similar to that of primary caries [51]. Furthermore, it is unrelated to the width of the crevice between the tooth and the restoration [52–56], except when "macroleakage" prevails, i.e. the width of the crevice exceeds 400 μm [57] or 250 μm [58]. Thus, "microleakage", which was believed to be important in the development of secondary caries, appears not to be a significant factor in the etiology of secondary caries. Furthermore, "ditching", which is a characteristic feature of occlusal cavosurface margins, does not result in secondary caries [59,60].

Secondary caries is localized and is usually situated gingivally on all types of restorations in permanent teeth, except for Class I sites where secondary caries is rare [59,60]. These clinical observations point to factors other than "microleakage" being the primary etiological factor. In fact, evidence available indicates that secondary caries occurs through the same biological process as primary caries, the difference being its location at the cavosurface margin of a restoration. The same criteria should therefore be used to diagnose primary and secondary caries; namely consistency, color, and wetness of the lesion. Active and arrested lesions should be differentiated, because arrested caries lesions do not require operative treatment, except for esthetic reasons. The recognition of these known facts calls for a revision of how we diagnose secondary caries and how we should treat it. Major changes are on the horizon in this context, changes that may have significant implications for the practice of dentistry.

The effect of fluoride being leached from restorative materials, such as glass ionomers, was expected to reduce the incidence of secondary caries. However, Mjör [61] published preliminary results revealing that glass ionomer restorations were most often replaced because of the clinical diagnosis of secondary caries. Several "letters to the editor" were submitted to the journal that published the results challenging these findings [62–66]. Analysis of the final data set confirmed the preliminary results. The fact remains that no controlled clinical study has shown a reduction in the clinical diagnosis of secondary caries associated with glass ionomer materials, except for xerostomic patients [67]. A positive effect in the prevention of caries lesions in newly erupted teeth adjacent to glass ionomer restorations has also been shown [25]. Similar effects on lesions of adjacent teeth have been shown in an in vitro/in vivo study design [68]. However, glass ionomers can reduce the incidence and severity of secondary caries lesions experimentally induced in vitro [69]. Remineralization of demineralized enamel in vitro by fluoride-releasing resin has also been reported [70,71], but the clinical follow-up on primary teeth showed less convincing results [72] and the effect attributed to fluoride release from the restorative material was difficult to differentiate from the fluoride in dentifrices. These results underline the need for clinical documentation, and practice-based research is expected to play an important role in this context.

Practice-based research

Practice-based dental research requires a large number of clinicians linked together in a network reporting on

the diagnoses and treatments they perform. Experienced clinical researchers provide guidance and statistical support for the investigations initiated by the clinicians. The value of practice-based research networks has been emphasized [73] and in a modified version adapted to dentistry, it reads: "*Practice-based research networks are research laboratories as essential to advancing the scientific understanding of* dental *care as bench laboratories are to advancing knowledge in the basic sciences*".

Practice-based research has many advantages, not only by tapping the experience base found in general dental practice, but also because of its potential effect on the research agenda in a wider context. This approach will map out the problems faced in general dental practice, and it will benefit from the fact that it has originated in dental practice. Apart from providing information about the treatment received by patients in non-academic dental settings, it will direct the scientific research in directions that will allow feedback to clinical practice more easily than if the research had been initiated and performed in a laboratory. In fact, important findings from practice-based research will identify areas that require basic science research to improve the oral health care that is provided, and provide a sound evidence base for future treatment.

Research in clinical practice has the decided advantage that it is linked to problems associated with real-life situations. On the other hand, practice-based research is hampered by a number of uncontrollable factors that expose it to scientific criticism: (1) variation in clinicians' treatment decisions, (2) lack of standardization and calibration of criteria used in treatment decisions, (3) variation in the assessment of quality, (4) differences in the perception of which defects and size of defects constitute failures that require replacement of the entire restoration, (5) differences that might arise because the clinician evaluates his/her own work rather than the work of others, and (6) the misunderstanding of definitions and instructions provided in a research protocol [74–77]. These are valid objections from a scientific point of view, and they highlight a need for an evidence base. This need has been recognized for decades, but it has not been attacked directly by identifying and defining the problems encountered in large-scale practice-based studies.

In practice-based studies the actively engaged clinicians must be directly involved in the design of the investigation. They must be encouraged to collect, collate, and substantiate their clinical experiences. Such experience bases must be established by a small group of clinicians and then be evaluated in short-term programs with a large number of peers in clinical practice to verify the experience base. This approach alone may solve the problem in question by pooling together the experiences and any related, existing knowledge, or it may be referred for scientific investigations to provide the evidence base.

Different approaches have been proposed to resolve the lack of an evidence base for many treatments in general dental practice [78] and the interest for systematic reviews is increasing [79,80]. The models proposed in these publications focused on previously published investigations, and they included statistical methods to combine data from two or more clinical investigations; meta-analysis being a common approach. However, it is essential that the clinical investigations included in such analyses be rooted in real-life clinical practice and they are usually not. Since practice-based studies are difficult to get published, on the grounds that they do not meet the scientific requirements set by journals [80], little information is available related to problems encountered in general dental practice. Thus, the meta-analysis approach of investigations that are not in accord with general clinical practice will be of limited value in improving everyday practice.

Practice-based research is essential to identify clinical problems. After a problem has been verified by a number of clinicians in general practice, work can be initiated to establish an evidence base. The Delphi technique is useful to formulate the topics to be examined [81]. Additional investigations, including basic science research will often be needed to achieve significant improvements in the dental care provided. Clinical problems that are not identified and presented to the research community are unlikely to be resolved! The sequence of events is important in this connection, and the best starting point lies in practice-based research.

Clinical experience

The establishment of a consensus among large groups of clinicians, which may be termed "confirmed clinical experience", must be the second step after identification of a clinical problem. This approach faces a problem, because publication of case reports in restorative dentistry is difficult, even if based on multiple cases by many clinicians. Such reports are excluded from journals and from meta-analyses because they do not fulfill scientific criteria. Some case reports may be found in national, state, and local dental journals [e.g. 82,83]. Systematic reviews of such reports as the first step in the identification of problems in real-life clinical practice are lacking and would be time-consuming, because many of the small, local journals will not be indexed. A practice-based approach to clinical research will open up experience bases that have so far rarely entered the dental research arena, i.e. opening up possibilities for studies that scientifically investigate, and presumably verify, clinical effectiveness. Therefore, interaction between networks of clinicians becomes an important element in practice-based research.

Technology transfer must be an integral part of practice-based research, and the most important step

in technology transfer has always been to reach the clinician in practice, but the transfer of relevant research is also required to update dental school faculty in restorative dentistry. The outlined stepwise approach is important for the dissemination of results, starting with practitioner-initiated projects, progressing to confirmation of the clinical evidence, and finally to scientific documentation whenever feasible. These procedures constitute the sequence of events that are necessary to improve dental care. The "clinically confirmed stage" will be the stage when clinicians in general should be introduced to a new approach as a feasible, appropriate treatment. By the time the scientific evidence becomes available, the new information should be part of clinical teaching and form the core of textbooks. Provided the treatment is considered safe and effective by both patients and clinicians, improvements in dental health care will prevail. However, an effective system for reporting physical/technical and biological side effects must also be an integral part of practice-based dissemination of knowledge and experience.

Concluding remarks

The sparse experience related to practice-based research in dentistry received a major boost when the NIDCR released a request for applications (RFA) related to practice-based dental research. RFA-DE-05-006 was issued on 18 November 2003 and it invited applications to establish and support a dental Practice-Based Research Network (PBRN). The initial stage will be to establish an infrastructure to conduct clinical trials and prospective observational studies. Representatives of the participating clinicians will determine the research agenda. The PBRN application had to be submitted together with a Coordinating Center application that outlines responsibilities for the development of manuals of procedures, including statistical designs. The applications for funding were due by 16 July 2004 and are currently under review. The earliest date for starting these studies is March 2005. Hopefully, this funding announcement will harbinger a fundamental shift towards recognizing the major role that practice-based dental research can have in advancing oral health science worldwide.

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